Australian Government

Department of Health and Aged Care

Office of Drug Control

COST RECOVERY IMPLEMENTATION STATEMENT

Regulation of Medicinal Cannabis

2024 - 2025

Effective from 1 July 2024

Office of Drug Control

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1. Introduction

The Cost Recovery Policy along with the Australian Government Charging Framework (the AGCF) sets out the policy under which government entities design, implement and review charging for regulatory activities. The Cost Recovery Implementation Statement (CRIS) is the public document to ensure the transparency and accountability for the level of the charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

The AGCF promotes consistent, transparent, and accountable charging for regulatory activities and supports the proper use of public resources. The Government's Charging Policy is based on the foundation that those who create the need for regulation, should bear the cost of that regulatory effort. The Australian Government have agreed to the 'Charging Policy Statement' that all charging arrangements must adhere to:

> *"Where specific demand for a government activity is created by identifiable individuals or groups, they should be charged for the costs of that activity unless the Government has decided to fund that activity".*

The AGCF is the Government's policy outlining how a regulator determines costs and sets fees and charges for its regulatory activities. Fees for regulatory charging activities are set to only recover the minimum efficient costs of carrying out that regulatory activity. The Medicinal Cannabis Program's cost recovery arrangement aligns with the AGCF and the Government's Charging Policy.

1.1 Purpose of the Cost Recovery Implementation Statement

This Cost Recovery Implementation Statement (CRIS) provides information on how the Department of Health and Aged Care (the Department) implements cost recovery charging for administering the Medicinal Cannabis Scheme (the Scheme) under the *Narcotic Drugs Act 1967* (the Act). It also reports financial and non-financial performance information for the Scheme and contains financial forecasts for the 2024-25 financial year and three forward years.

1.2 Single Convention on Narcotic Drugs

Australia is a party to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol (the Single Convention). This convention aims to limit harm from illicit use or abuse of narcotic drugs while setting out the scope of permitted activities, such as for medical and/or scientific use.

As a party to the Single Convention, there are two key responsibilities for the Australian Government. The first is an obligation to carefully control, supervise and report on cultivation, production, and manufacture of narcotic drugs, including medicinal cannabis. The second is to take measures to prevent the stockpiling or diversion of narcotic drugs, including medicinal cannabis, for illicit purposes.

The Act was enacted in 1967 to give effect to certain of Australia's obligations under the Single Convention. Significant amendments were made to the Act in 2016 to allow for the establishment of the Scheme and provide a pathway for lawful supply of medicinal cannabis to Australian patients. The amended Act was designed to ensure that Australia will remain compliant with its international treaty obligations in the Single Convention.

In accordance with the Single Convention, the Office of Drug Control (ODC) within the Department of Health and Aged Care (the Department) is the agency that has sole responsibility for the regulation of the cultivation and production of medicinal cannabis for medicinal and research purposes. No other Government agencies are involved in this partial cost recovery arrangement. The Department implemented and continues to administer the Scheme, which includes a licence and permit framework that allows for the cultivation, production, and manufacture of medicinal cannabis in Australia. The Scheme helps ensure Australian patients have access to essential medicine while supporting the Australian Government's policy of harm minimisation.

1.3 Outline of the regulatory activities

Medicinal Cannabis Licences

An applicant may make an application for a licence to undertake one or more of medicinal cannabis cultivation, production, or manufacture activities. The Secretary of the Department or a Delegate of the Secretary (a Delegate) must make a decision on that application. In deciding, the Delegate must be reasonably satisfied with the following factors:

- the applicant, and the applicant's relevant business associates, must be considered fit and proper persons to either hold a licence or be associated with a licence. This involves consideration of a range of matters including criminal history, connections, associates and family, financial status, business history and capacity to comply with licensing requirements. Licence holders are to remain 'fit and proper' for the duration of the licence. This test is explicitly designed to ensure the exclusion of persons who may be tempted to use the Scheme as cover for illegal activities.
- it must be established that the applicant can maintain the physical security of the cannabis plants, cannabis, or cannabis resin and/or medicinal cannabis drug.
- any other matters detailed in the Act or prescribed by the regulations.

Medicinal Cannabis Permits

Once a licence is granted, a licence holder shall only undertake the activities authorised under the licence in accordance with one or more permits. To obtain a permit, a licence holder must submit a permit application and a Delegate must make a decision on that application. In deciding to grant a permit, the Delegate will set limits on the scope of the activities that can be undertaken, including:

- the quantity of cannabis plants that can be cultivated
- the quantity of cannabis and/or cannabis resins that can be produced
- the maximum quantity of the drug that may be manufactured.

Additionally, it must be established that a legitimate supply arrangement exists between the applicant for a medicinal cannabis permit and the holder of a licence to produce or manufacture medicinal cannabis. This is to prevent the diversion of cannabis and to ensure that the activities are related to the medicinal use of cannabis.

Cannabis permits are only granted for production where there is a contract between the licence holder and an authorised producer or licensed manufacturer. Permits are granted for a 12-month period and require subsequent applications to be submitted and approved to

continue permitted activities. This assists in meeting a key obligation of the Single Convention to prevent over-production and diversion to illicit uses.

Monitoring and Compliance

Cannabis licences are subject to statutory conditions and a Delegate can impose conditions on the licence to promote security of the crop, cannabis, and cannabis resins, so that it is not diverted to illicit uses. Substantial penalties exist for contravention of these conditions and offences relating to activities that are not authorised by the medicinal cannabis licence.

Regulatory Enabling Services

The ODC delivers a range of enabling services that directly supports the regulation of medicinal cannabis, including the development and implementation of governance, policy and procedural materials, legislative reforms to streamline the regulatory framework, data analytics, program reporting and Government briefings, enquiries management and intergovernmental agreements with law enforcement and other Commonwealth, state and territory agencies. In addition, the ODC delivers a range of financial management services associated with the fees and charges applied to the regulation of medicinal cannabis licence holders.

Excluded Activities for this CRIS

For clarity, the following activities are not included in the Scheme's cost recovery arrangements as they are conducted under separate legislation:

- costs for activities related to the import and export of medicinal cannabis under the *Customs (Prohibited Imports) Regulations 1956* and the *Customs (Prohibited Exports) Regulations 1958*.
- costs for activities authorised under the *Therapeutic Goods Act 1989*, such as licences to manufacture therapeutic goods (under Part 3-3 of that Act) and costs for patient access to medicinal cannabis drugs through the Therapeutic Goods Administration's (TGA's) Authorised Prescriber Scheme and Special Access Scheme.

2. Policy and statutory authority to cost recover

2.1 Government policy approval to cost recover

In the 2015-16 Mid-Year Economic and Fiscal Outlook, the Government announced its intention to establish a Commonwealth licensing scheme, to be administered by the Department[1], to regulate the cultivation of cannabis for medicinal and scientific use.

Additionally, in the 2016-17 Budget, the Government announced that it would introduce legislation to allow charges to be imposed on cannabis-related licences granted under the Act. Any revenue collected will support the Scheme for the regulation of cannabis for medicinal and scientific use.

Given the greater than anticipated interest in the Scheme, in the 2018-19 Mid-Year Economic and Fiscal Outlook, the Government increased resourcing to administer the Scheme and

[1] Mid-Year Economic and Fiscal Outlook 2015-16, https://archive.budget.gov.au/2015-16/myefo/MYEFO_2015-16_Final.pdf, p.180.

required the Department to review the cost recovery arrangements[2]. As a result of the review, the Department developed a proposal for amendments to fees and charges for the Scheme and undertook a detailed program of stakeholder engagement.

In the 2020-21 Budget, the Government announced the extension of cost recovery arrangements to medicinal cannabis-related manufacture licences and increased resourcing to meet the ongoing demands of administering the Scheme. Changes to fees and charges were outlined that commenced on 1 November 2020.

In the 2023-24 Budget, the Government approved revised cost recovery arrangements to align cost recovery fees and charges with the associated costs of managing the single, perpetual licence model for medicinal cannabis regulation and revised permits framework. Subsequent changes to fees and charges commenced on 1 August 2023.

There are no changes to the partial cost recovery arrangements that relate to non-commercial medicinal cannabis licences. It was determined that full recovery may reduce investment in research. The shortfall in costs will continue to be met through appropriation from the Australian Government.

2.2 Statutory authority to charge

The Act[3] allows for regulations that provide for the imposition of fees for any matters within it, including matters relating to the payment of fees and charges. *The Narcotic Drugs Regulation 2016* (Narcotic Drugs Regulation) is the instrument that specifies the fees related to applications and inspections.

The *Narcotic Drugs (Licence Charges) Act 2016* (Licence Charges Act) provides authority to impose a charge on a licence granted under the Act and that is in force within a specified period. The licence charge assists the Commonwealth in recovering the costs of the administration, monitoring and assessment of compliance with the requirements of the Act, the Narcotic Drugs Regulation, the licence, and any permits. Section 8 of the Licence Charges Act allows regulations to prescribe the amount of charges.

The *Narcotic Drugs (Licence Charges) Regulation 2016* (Licence Charges Regulation) specifies the period the charge is imposed, the amount and how the charge is calculated. It also provides for non-commercial medicinal cannabis licence holders to pay one licence charge for the period for which the licence is in force, instead of for each 12-month period that the licence is in force as with perpetual commercial medicinal cannabis licences. A non-commercial medicinal cannabis licence is defined in section 54A of the Narcotic Drugs Regulation. Non-commercial medicinal cannabis licences are generally not perpetual but issued for a relevant period related to the research project timeline to be undertaken.

3. Cost recovery model

The cost recovery arrangements provide for the imposition of both fees and levies (charges). The characteristics of a government activity determine the type of cost recovery charge used. There are three types of cost recovery charges applied to regulate the Scheme:

[2] Mid-Year Economic and Fiscal Outlook2018-19, https://archive.budget.gov.au/2018-19/myefo/myefo_2018-19.pdf, p.189.
[3] *Narcotic Drugs Act 1967*, Section 28 (1)(c), (d) and (e).

Cost recovery fees will be charged where a direct relationship exists between the regulatory activity and the individual or organisation requesting that specific activity. All regulated entities are charged the same fee for the same activity. Under these circumstances, the activities performed, and their associated costs are driven by a specific need and demand created by the applicant. For example, applications for a Medicinal Cannabis licence will be charged a cost recovery fee.

A cost recovery fee is also payable for an inspection undertaken in relation to an application for a licence, permit or a licence/permit variation application (an application-based inspection).

Cost recovery charge (levy) will be charged when the cost of the activity can be reasonably attributed to a broader group of organisations (or individuals) rather than a single entity. In these instances, the level of demand for Government activity or intervention is collectively driven by the industry as a whole rather than a single entity within it.

Inspection charges (levy) (e.g., Specific Cost Recovery Levy) – a charge that recovers the minimum efficient costs of routine regulatory inspections and verifications. This cost recovery charge is based on the regulatory cost associated with the administrating and conducting of inspections or verification activities (such as for tip-offs). The charge will be imposed at the point-in-time the inspection or verification occurs.

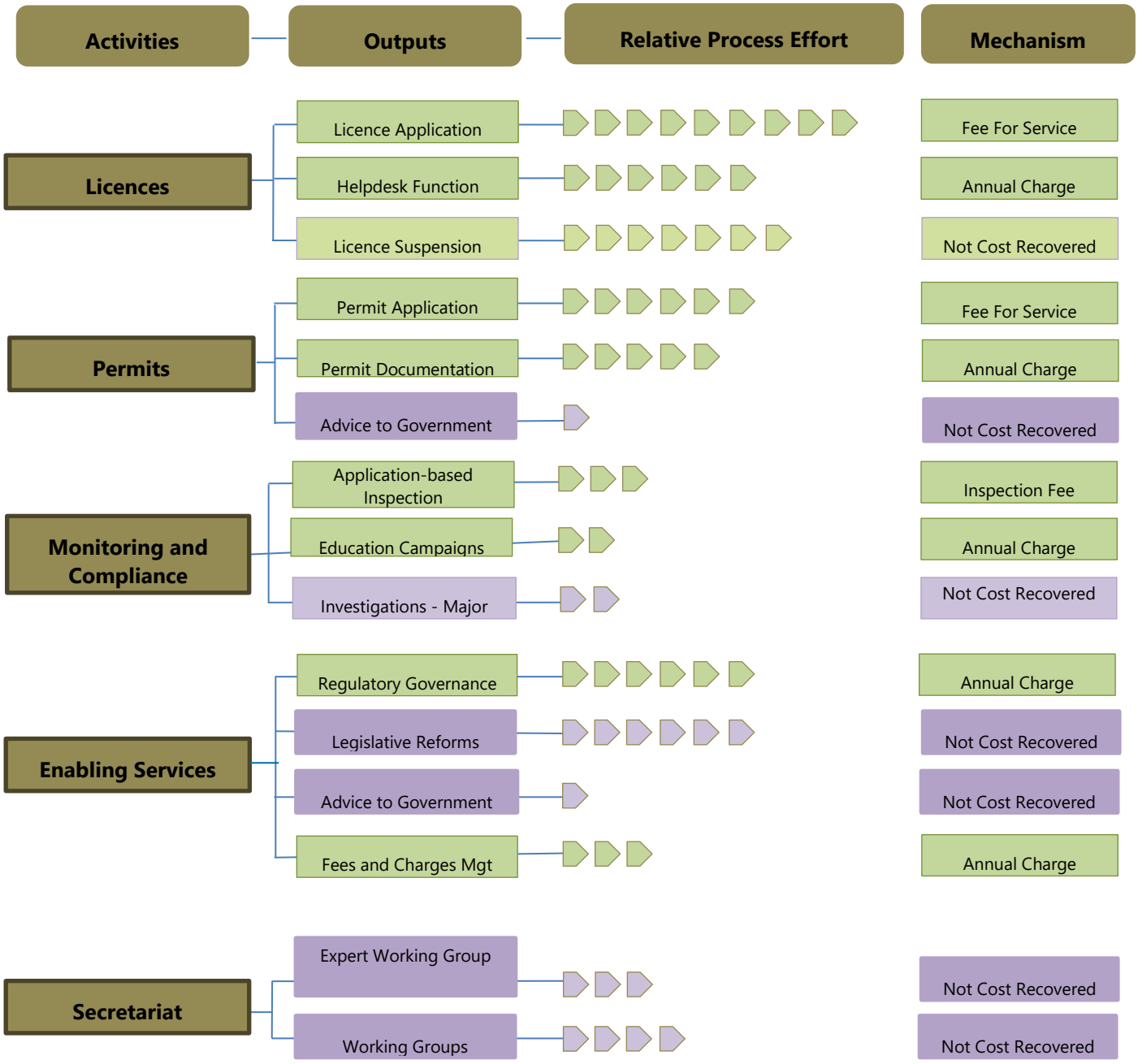
3.1 Outputs and business processes of the regulatory activity

Outputs

The activity-based cost recovery model has been developed based on the key business activities that result in a number of outputs. Each output is delivered through the completion of tasks or staff effort.

Figure 1 is a condensed example of the activities, outputs and tasks, the respective effort, and whether costs are recovered. This is not a complete list of all activities and outputs, rather it is an illustration of some business processes.

Figure 1: Condensed ODC Business Processes



3.1.1 Output 1 - Applications

The Scheme allows for several different applications that have similar processes. However, the effort and time required for each process varies depending on the nature of the application.

The process related to an application is as follows:

- receipting - which includes filing all documentation and handling payment of invoices
- qualitative screening of the applications
- assessment of the application
- decision by a delegate to grant or refuse to grant a medicinal cannabis licence, permit, or variation to a medicinal cannabis licence or permit
- notification of decision made.

Application for a medicinal cannabis licence

Any person interested in undertaking cultivation, production, or cannabis–related manufacture under the Scheme must apply for a medicinal cannabis licence authorising any or all of these activities and a Delegate must make a decision on the application. While each medicinal cannabis licence application considers different information that reflects the nature of the activity to be authorised, the Department's internal cost recovery review found that, in general, the average efficient time for assessing an application is comparable.

The assessment of a medicinal cannabis licence application includes consideration of the applicant as a fit and proper person to hold a licence, the ability of the applicant to maintain security of the cannabis, cannabis resin or cannabis drugs, and alignment of the proposed activities with Australia's obligations under the Single Convention.

Application to vary a medicinal cannabis licence

A licence holder can apply to vary a medicinal cannabis licence. The effort required for the handling of such an application differs significantly, depending on the nature of the variation. In order to streamline the design of fees, the significant variable regulatory effort was identified in licence variations and have been established to group similar effort into the same fee amount. Licence holders will be required to pay for each variation requested to a licence or permit. In circumstances where multiple variations to a licence or permit are requested, the applicant will pay for each variation applied for. As a result, the application fee to vary a medicinal cannabis licence is divided into four categories with differing costs:

- licence variation type 1 – an application to vary a medicinal cannabis licence for any of the following purposes
    - to change the licence holder name (without changing the legal entity)
    - vary or remove a person authorised by the licence to engage in authorised activities
- licence variation type 2 – an application to vary a medicinal cannabis licence for any of the following purposes
    - vary or add to the period in which a licence is in force (for non-commercial licence holders)
    - vary, add, or remove particular measures to the approved system of security
    - any other variation not specified in licence variation types 1, 3 or 4

- Licence variation type 3 – an application to vary a medicinal cannabis licence for any of the following purposes
    - vary the layout of site
    - vary the floorplan of facility
    - vary, add, or remove a particular activity authorised by the licence
    - add one or more authorised person/s
- Licence variation type 4 – an application to vary a medicinal cannabis licence for the following purpose
    - add an additional licensed site.

Application for a medicinal cannabis permit

Any activities authorised under a medicinal cannabis licence must be undertaken in compliance with a valid cannabis permit. As such, once a medicinal cannabis licence is granted, a licence holder may apply for one Cultivation and Production Permit and/or one Manufacture Permit, per site. If an initial permit is granted, the permit will be active for a 12-month period. Should the licence holder want to continue activities under a permit following the 12-month initial permit period, a subsequent permit application for the next 12-month period is required for submission.

Medicinal cannabis permits are used to control the quantities of cannabis plants cultivated, cannabis or cannabis resin produced and quantities of cannabis drugs that are manufactured. A medicinal cannabis permit is a critical tool in ensuring Australia complies with its international obligations under the Single Convention. The assessment of a medicinal cannabis permit will verify that the source/s of the cannabis plants, cannabis or cannabis resin are licit and require evidence of contracts between entities that are supplying or receiving cannabis plant, cannabis, or cannabis resin.

As there is more regulatory effort expended on initial permit applications than there is on subsequent permit applications for both Cultivation and Production and for Manufacture permits, separate fees exist. Therefore, the application fee to apply for an initial and subsequent Cultivation and Production Permit, and a Manufacture Permit, is divided into 4 categories:

- Permit application (Cultivation and Production) – Initial
- Permit application (Cultivation and Production) – Subsequent
- Permit application (Manufacture) – Initial
- Permit application (Manufacture) - Subsequent

Applications to vary a medicinal cannabis permit

As with a medicinal cannabis licence, a licence holder can apply to vary a medicinal cannabis permit and the effort associated with handling that application differs significantly in the nature of the variation. These fees have been structured to reflect the regulatory effort required to administer these variations. Similar to licence variations, permit holders will be

required to pay foreach variation requested. Similarly, the application fees to vary a medicinal cannabis permit is divided into three categories:

- Permit variation type 1 - application to vary a medicinal cannabis permit for any of the following purposes:
    - to change the licence holder name (without changing the legal entity)
    - change to maximum numbers, units or quantities specified in the permit at any one time with no change to total quantities that the licence holder is authorised for during the period of the permit.
- Permit variation type 2 - application to vary a medicinal cannabis permit for the following purpose:
    - add or remove a particular supply pathway specified by the permit
- Permit variation type 3 - application to vary a medicinal cannabis permit for the following purpose:
    - change to total quantities, type of cannabis plants, total number of cannabis plants, or total units of seeds
    - vary, add, or remove a particular activity specified by the permit to be undertaken at a particular licensed premises.

3.1.2 Output 2 - Inspections

An inspection is undertaken to verify matters relating to medicinal cannabis licences or permits. It is Departmental policy that two Authorised Inspectors attend all inspections given the potential seriousness of the non-compliance and all charges are indicative of this effort. The manner in which the costs of inspections are recovered varies depending on the context of the inspection and effort undertaken.

Specific inspection charges will apply to monitoring and inspection events. These specific cost recovery charges recover the minimum efficient costs of regulatory inspections and verifications. This cost recovery charge is based on the regulatory cost associated with the administrating and conducting of routine regulatory inspections or verifications (either virtually/desktop or onsite). This charge is imposed at the point-in-time the inspection or verification occurs.

Application-Based Inspection (Inspection Fee)

Upon an application being made for an initial cannabis permit, and prior to making a decision on the application, the Department will conduct an application-based inspection of the premises. This is to inform the decision on the permit application by ensuring that the site is ready for operation by being compliant with the conditions of the medicinal cannabis licence and being in accordance with the proposed site/facility plans provided with the application. An application-based inspection can also be required in relation to other types of licence/permit related applications, as determined by a risk-based compliance approach.[4] An application-based inspection is subject to an inspection fee as they are in direct response to a request from an individual or organisation.

[4] Risk management approach to the cultivation, production and manufacture of medicinal cannabis | Office of Drug Control (odc.gov.au) 2021.

Historical data has demonstrated that permit application-based inspections occur within a similar timeframe and are usually shorter in duration compared to compliance monitoring inspections, in particular for an inspection related to an initial permit application as there will be no cannabis plants, cannabis, or cannabis resin on site at the time of such an inspection.

Monitoring and Compliance Inspection Type 1 and Type 2

Every licence holder is subject to routine regulatory compliance monitoring inspections on an ongoing basis once a licence has been granted, whereby Authorised Inspectors undertake an inspection using monitoring powers as outlined under Division 2, Subdivision A of the *Regulatory Powers (Standard Provisions) Act 2014* (the Regulatory Powers Act). Associated costs are included in the routine regulatory (inspection type 1) or verification (inspection type 2) inspection charges (levies), depending on the matter. The inspection type 1 and type 2 charges will be imposed at the point in time the inspections take place.

A verification inspection is undertaken to verify the veracity of information, for example to verify information received through public concern (tip-offs) or to verify actions undertaken by the licence holder.

Inspection related travel costs

Applicants and licence holders will not pay any inspection related travel costs. The Department has been provided appropriated funding for this cost, to remove any financial disadvantage for applicants, or licence holders in rural or remote locations who would be subject to higher travel costs based on their location.

Inspection related travel costs include accommodation, airfares, train fares, car hire, taxi or other car services, tolls, meals, or other allowances for departmental employees, and whole of government booking fees.

3.1.3 Output 3 – Annual licence charge

Annual licence charge

An annual charge is applied to recover the costs of specific activities that are essential for robust regulation of the sector. The annual charge applies to all licence holders irrespective of whether they hold permits or not. These costs exist irrespective of the number of licences or permits approved. These activities include, but are not limited to, enquiries management; web services and IT costs; industry education including compliance campaigns; and regulatory governance including enquiries and financial management, conducted by the ODC to ensure it meets the policy and legislative responsibilities in delivering efficient regulation.

The annual licence charge is imposed on all licence holders when a licence is granted and each year thereafter on the anniversary date of the licence. It is an obligation for all licence holders to pay the charge in full on the anniversary date of their licence. Once the charge is invoiced, a debt to the Commonwealth is incurred and the relevant invoice must be paid.

More specific detail is set out below on some of the activities the cost of which are included in the annual licence charge, namely:

- response to mandatory notification
- licence suitability review
- regulatory governance
- compliance education campaigns

- continuous improvement.

3.1.3.1 Response to mandatory notification

In accordance with section 10K of the Act and section 20 of the Narcotic Drugs Regulation, it is a condition that all licence holders notify a Delegate of certain matters. As the Department must respond to these notifications, the cost of such responses is included in charges to licence holders. Not all matters relate to non-compliance. However, the Department must review each matter and respond accordingly.

Some of the matters that a licence holder must notify a Delegate of relate to the loss or theft of cannabis plants, cannabis, or cannabis resin. Other matters relate to the licence holder itself, such as notification of new shareholders and business associates. As a result, the recovery of costs associated with a response to mandatory reporting is assigned to the annual charge.

The following activities are associated with a response to mandatory notification:

- receive and register the notification
- review and analyse the notification
- make a determination on the matter
- refer matter of potential non-compliance to the relevant team for action (where relevant)
- notify licence holder of outcome

3.1.3.2 Licence suitability review

Most medicinal cannabis licences have perpetual operation. This means that the licence continues without an end date, but subject to the operation of the suspension, revocation and voluntary surrender frameworks in the Act and the Regulation.

Nevertheless, periodic reviews of a licence holder's circumstances will be undertaken to ensure the licence holder's information and records are up to date and that the licence holder continues to be suitable to hold the licence. This will include requesting and assessing information relevant to whether the licence holder continues to be fit and proper person/s and to ensure the licence and permit are up to date and do not require specific variation.

3.1.3.3 Regulatory governance

Review of mandatory cannabis permit reporting

Once a cannabis permit is granted, permit holders are obliged to provide reports on their activities in accordance with that cannabis permit. The Department will assess these reports on a quarterly basis as follows:

- receive and register reports,
- review and analyse the report,
- make determination on matter,
- where relevant, refer matter of potential non-compliance to the relevant team for action,
- notify licence holder of outcome.

Enquiries management

To ensure medicinal cannabis stakeholders have proper guidance, advice, and information to readily submit complete applications, as well as recognising the obligations of all licence holders, there is significant regulatory effort to respond to and manage enquiries. As the ODC must respond to these enquiries and can often lead to complex discussions, consultations, and further requests for information, the costs of this effort is included in the annual licence charge.

Financial management

The ODC undertakes many activities required to invoice appropriate fees and charges, negotiate payment plan arrangements, manage debt recovery, facilitate education and guidance regarding fees and charges, and manage the cost recovery arrangements. The cost of this effort is included in the annual licence charge that applies to all licence holders.

3.1.3.4 Education and compliance campaigns

As the result of an inspection, virtual (desktop) audit, cannabis permit report or a follow up audit, the Department may identify actions or behaviours on the part of a licence holder that, while not a matter of non-compliance, raises some concerns. In these instances, the Department may elect to undertake an educative approach with the licence holder or seek that the licence holders take corrective actions. Compliance related educative campaigns may be undertaken across wider groups of licence holders or the industry in relation to particular issues.

The following activities are associated with this business process:

- receive and review matter,
- liaise with licence holder,
- where relevant, provide documentation outlining corrective action to licence holder,
- reconcile evidence that corrective action has been undertaken,
- refer matter of potential non-compliance to the relevant team for action (where relevant) notify licence holder of outcome.

3.1.3.5 Continuous improvement

To ensure that the Department remains an agile and responsive regulator, the costs of undertaking continuous improvement of the Scheme by the Department has been incorporated into the cost recovery arrangements.

The following activities are associated with this business process:

- development and maintenance of publicly available guidance
- stakeholder engagement activities
- activity based costing processes and ongoing management of the cost recovery arrangements
- development and maintenance of online service portal for customers and a case management system (once implemented)

3.2 Costs of the regulatory charging activity

Activity Based Costing

An activity-based costing exercise was undertaken as part of the 2022 review of the Medicinal Cannabis Program Regulatory Fees and Charges to determine the average efficient time spent by a departmental employee on each task. Staff effort was identified against 555 tasks relevant to the single perpetual licence framework and permit reforms. This exercise allowed the Department to determine the direct and indirect costs of regulating the Scheme. Some indirect costs, such as the Secretariat function for the Medicinal Cannabis Expert Working Group, are not included within the cost recovery arrangements and appropriation funding has been provided by the Government.

It is government policy that fees and charges are indexed annually to reflect the efficient costs of providing the services and undertaking the activities required to regulate the medicinal cannabis industry.

The revised costs associated with the 2024-25 activity- based costing model incorporates indexation in line with the government policy.

Cost drivers and assumptions

In determining the cost drivers, several assumptions were made based on historical data and experience from undertaking such activities. The Department has forecast the expected volumes of applications within the single licence framework, the time taken to undertake specific activities and the behaviours of the medicinal cannabis sector in determining the forecast volumes. For example, the Department determined forecast volumes of subsequent permit applications based on the relevant active permit numbers and the 12-month period each permit is granted for.

These estimates are highly sensitive to the growth of both the domestic and global medicinal cannabis markets, which are limited by the requirements of the Single Convention and regulated by the International Narcotics Control Board (INCB).

Tables 1 and 2 summarise the direct and indirect costs of each fee and charge for the 2024-25 financial year. Note that the final amounts for the majority of each fee and charge is rounded to the nearest $10, as set out in tables 3 to 5 below.

Table 1: Unit Cost for 2024-25

Output 1 - Applications	Direct costs	Indirect costs	Unit costs
New Licence Application	$ 10,588	$ 2,976	$ 13,564
Licence Variation Type 1	$ 466	$ 128	$ 594
Licence Variation Type 2	$ 1,181	$ 331	$ 1,511
Licence Variation Type 3	$ 1,733	$ 486	$ 2,220
Licence Variation Type 4	$ 9,551	$ 2,729	$ 12,280
Permit Application (Cultivation and Production) – Initial	$ 9,655	$ 2,452	$ 12,106
Permit Application (Cultivation and Production) – Subsequent	$ 7,197	$ 2,072	$ 9,269
Permit Application (Manufacturing) – Initial	$ 6,377	$ 1,620	$ 7, 997
Permit Application (Manufacturing) – Subsequent	$ 4,755	$ 1,361	$ 6,116
Permit Variation Type 1	$ 495	$ 137	$ 632
Permit Variation Type 2	$ 1,326	$366	$ 1,692
Permit Variation Type 3	$ 4,089	$ 1,158	$ 5,248

Table 2: Unit Cost for 2024-25

Output 2 - Inspections	Direct costs	Indirect costs	Unit costs
Application Based Inspection (Inspection fee)	$ 7,551	$ 1,824	$ 9,375
Routine/Ongoing Inspection (Inspection type 1)	$ 10,305	$ 2,509	$ 12,814
Inspection (Verification) (Inspection type 2)	$ 3,901	$ 938	$ 4,839
Output 3 – Annual licence charge			
Annual licence charge	$ 23,327	$ 4,501	$ 27,828

Non cost recoverable activities

The non-recoverable activities are those activities that cannot be directly attributable to the regulation costs of Licence holders. There are several regulatory administrative activities that are not cost recoverable within the context of the AGCF. These administrative items include Administrative Appeals Tribunal costs, providing advice to Government, the Medicinal

Cannabis Expert Working Group, moderate and major investigations, and prosecuting court action enforcements. Non cost recoverable items are funded by the Australian Government.

3.3 Design of regulatory charges

Cost recovery for the regulation of the Scheme aligns with the Government's overarching cost recovery policy which is, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of such activities. The cost recovery policy promotes consistent, transparent, and accountable charging for Government activities and supports the proper use of public resources. Fees and charges are imposed on applicants and licence holders who engage with the Scheme.

Fees

The Department uses fees to recover costs when services are provided directly to an individual applicant or licence holder. A fee is applicable where the activity is driven by an action of the applicant or licence holder.

All licence and permit applications and variations are subject to an application fee, to be paid by the applicant. An Application Based Inspection is also subject to a fee as they are in direct response to a request from an individual or organisation.

Charges (Levies)

There are two types of charges (levies) imposed on Licence Holders:

- Annual Charge - The annual charges (levies) are associated with costs that are not driven by the actions of individuals or entities, rather these pertain to the industry. As these outputs are delivered irrespective of the size, complexity or the regulatory maturity of the licence holder, the total annual costs of leviable outputs are shared between all licence holders. The proxy used to distribute the annual leviable costs will be the number of licence holder as of 31 March each year. On 31 March 2024 there were 84 licence holders.

- Monitoring and Inspection Charges - The costs of activities relating to the monitoring or response to potential or actual non-compliance of a licence holder are recovered using Monitoring and Inspection charges. There are several types of inspections that the ODC can conduct – each based on the costs of undertaking the inspection.

To provide reduced regulatory costs, non-commercial medicinal cannabis licence holders are only required to pay the annual licence charge once during the period of the licence, compared with the requirement for commercial licence holders to pay these charges annually (commercial licences being perpetual). The shortfall in revenue for each non-commercial medicinal cannabis licence is met by appropriation funding from government.

Fees and charges – from 1 July 2024

Table 3 outlines:

- The fees payable for new licence applications and four types of licence variation fees, as well as the forecast volumes and revenues for the 2024-25 financial year.
- The fees payable for permit applications and variations as well as the forecast volumes and revenue for the 2024-25 financial year.
- The 2024-25 annual charge, the forecast number of licence holders and the forecast revenue for the 2023-24 financial year.
- Application Based Inspection used when conducting application-based inspections.
- Routine/ongoing inspections used for compliance monitoring purposes, and which are also based on the minimum efficient costs of conducting these inspections.
- Verification Inspections[5] used when an inspection is required to verify that licence or permit conditions or legislative requirements have been met.

Whilst licence variations have been grouped together into respective types reflecting similar regulatory effort, each variation requested would include the relevant variation type price. For example, if a Licence Holder sought two different variations from Licence Variation Type 3 in 2024-25, the applicant would be charged $2,220 for each variation sought paying a total of $4,440.

For permit variations, similar to licence variations, each variation request would attract the relevant variation type fee amount and would be invoiced cumulatively.

Forecast Volumes for licences and permits activities and outputs have been based on existing program data information, including predictions in the number of different licence and permit applications. Variation volumes have also been based on existing data sources.

Table 3: Fees & Levy	Type	Unit cost	Charge Rate	Estimated volume	Estimated total cost	Estimated total revenue
Licence						
New Licence Application	Fee	$ 13,564	$ 13,560	25	$ 339,088	$ 339,000
Licence Variation Type 1 -Change licence holder name -Remove authorise persons from licence	Fee	$ 594	$ 595	10	$ 5,945	$ 5,950
Licence Variation Type 2 -Change period in which licence is in force -Vary or remove a particular condition of the licence -Modify, add new, or remove security measures -Any other non-specified requirement	Fee	$ 1,511	$ 1,510	28	$ 42,318	$ 42,280
Licence Variation Type 3 -Change of layout of site	Fee	$ 2,220	$ 2,220	62	$ 137,614	$ 137,640

[5] Verification inspections are either virtual or onsite inspections to verify veracity of information received or actions undertaken by the licence holder.

-Change of floorplan of facility -Add activity to licence -Add authorised person/s						
Licence Variation Type 4 -Add additional site	Fee	$ 12,280	$ 12,280	4	$ 49,121	$ 49,120
Permit						
Permit Application (Cultivation and Production) - Initial	Fee	$ 12,106	$ 12,110	7	$ 84,744	$ 84,770
Permit Application (Cultivation and Production) - Subsequent	Fee	$ 9,269	$ 9,270	37	$ 342,958	$ 342,990
Permit Application (Manufacturing) - Initial	Fee	$ 7,997	$ 8,000	5	$ 39,984	$ 40,000
Permit Application (Manufacturing) - Subsequent	Fee	$ 6,116	$ 6,120	14	$ 85,622	$ 85,680
Permit Variation Type 1 -Change to licence holder name -Change to maximum quantity at any one time with no Change to total quantity	Fee	$ 632	$ 630	6	$ 3,793	$ 3,780
Permit Variation Type 2 - Change to supply pathways only	Fee	$ 1,692	$ 1,690	6	$ 10,154	$ 10,140
Permit Variation Type 3 -Change to quantities or activities	Fee	$ 5,248	$ 5,250	44	$ 230,902	$ 231,000
Monitoring and Inspection						
Application based inspection (Inspection fee)	Fee	$ 9,375	$ 9,370	18	$ 168,748	$ 168,660
Routine/Ongoing Inspection (Inspection type 1)	Fee	$ 12,814	$ 12,810	46	$ 589,462	$ 589,260
Inspection (Verification) (Inspection type 2)	Fee	$ 4,839	$ 4,840	4	$ 19,354	$ 19,360
Annual Charge						
Annual Licence Charge	Levy	$ 27,828	$ 27,830	96	$ 2,671,443	$ 2,671,680
TOTAL ACTIVITY					$ 4,821,249	$ 4,821,310

4. Risk assessment

A Charging Risk Assessment for the Scheme has been undertaken resulting in a **LOW-RISK** rating. This rating is attributed mainly to the small increase (less than 3%) in fees and charges. In addition, no complex legislative changes were required, and the stakeholders did not raise any issues about indexation only increase.

5. Stakeholder engagement

The consultation and communication process for the proposed increases to the medicinal cannabis fees and charges for the 2024-25 financial year, to apply indexation, commenced with a notification to all licence holders and key industry bodies on 22 February 2024. The period of consultation ran through to 8 March 2024. No feedback was received from industry.

6. Financial Performance

6.1 Financial Estimates

Table 7 details the Program's financial estimates for the current budget year and three forward years

Table 7: Financial estimates for the program

Financial Estimates	2024-25 $'000	2025-26 $'000	2026-27 $'000	2027-28 $'000
Expenses (X)	5,600	5,865	6,135	6,249
Revenue (Y)	4,821	5,051	5,284	5,390
Balance (Y-X)	-779	- 814	-851	-859
Cumulative Balance	-$ 1,524	-$ 2,337	-$ 3,188	-$ 4,047
Explain balance management strategy	The Department has appropriation funding from the Australian Government to cover the cumulative balance variance resulting from partial cost recovery arrangements.			

6.2 Financial Outcomes

Previous financial performance is detailed in Table 8 from pre-reform activities. While the ODC has historical data in relation to these elements, the reforms to the program mean that past financial performance to 2020-21, will not be directly comparable to the transition/review 2022-23 financial year or to the budgeted 2023-24 financial year and forward estimates of the Program, due to not fully recovering the regulatory costs of the Program. In addition, the structure of fees and charges have also changed, as has the charging model.

Table 8: Financial Outcomes for the program

Financial item	2019-20 $'000	2020-21 $'000	2021-22 $'000	2022-23 $'000
Estimates				
Revenue (X)	$ 2,528	$ 4,857	$ 4,906	$ 7,467
Expenses (Y)	$ 2,595	$ 5,137	$ 5,188	$ 7,506
Balance (X-Y)	-$ 67	-$ 280	-$ 282	-$ 39

Actuals				
Revenue (X)	$ 2,086	$ 3,137	$ 3,162	$ 1,894
Expenses (Y)	$ 3,702	$ 4,548	$ 5,397	$ 5,340
Balance (X-Y)	-$ 1,616	-$ 1,411	-$ 2,235	-$ 3,446
Cumulative balance	-$ 3,875	-$ 1,411	-$ 3,646	-$ 7,092

7. Non-Financial Performance

Non-Financial performance of regulatory activity over 2022-23 – Volumes

Activity	**2022-23 Estimated****	**2022-23 Actual**	**2022-23 Variance**
Cannabis licence applications	16	19	+3
Cannabis permit applications	143	42	-101
Application for a variation to a cannabis licence	110	54	-56
Application for a variation to a cannabis permit	84	9	-75
Planned inspections	25	30	+5
Annual licence charge	153	95	58

*** Estimated volumes for 2022-23 were forecast based on the previous multiple licence and permit framework*

Performance measures

The Act does not include statutory timeframes for decision-making or application processing. The Department provides an indicative timeline for processing applications on the ODC website, from the date of receipt. However, this excludes any time where the application is referred back to the applicant for further information, or due to delays in receiving information requested from external Commonwealth, State and Territory agencies (including law enforcement agencies). These published timeframes are currently:

- medicinal cannabis licence application - approximately 205 working days (including receipting and generating invoices)
- application to vary a medicinal cannabis licence: approximately 70 working days to 205 working days depending on the complexity of the variation submitted.

In 2022 the ODC undertook a business process and systems transformation review to identify both system and process improvements allow the ODC to perform its functions in a more

effective and efficient manner. Industry representatives and other stakeholders were consulted as part of the review. The review made several recommendations on the possible future state of the ODC's processes and systems. Government funding was provided in the 2023-24 Budget to progress an ODC digital transformation and process reform program of work resulting from the transformation review. This program of work is currently under way and will result in the replacement of manual application submissions with smart forms, a case management system for the tracking of applications and regulatory actions, effective sharing of information across multiple software systems and data transferability, and several other system and process improvements to better support both industry and ODC staff.

International Scrutiny

The progress of the Scheme will be the subject of scrutiny from the INCB. Australia is required to provide annual datasets to the INCB outlining the quantities of cannabis plants cultivated, cannabis and cannabis resin that has been produced and cannabis drugs that have been manufactured in a calendar year.

The INCB then makes comments in its annual report on the performance of Australia against the requirements of the Single Convention. If the INCB make a negative comment on Australia's performance, for example that production of cannabis resin has exceeded the medical need, then remedial action may need to be considered. Such an event could impact on the data provided in this document.

8. Key forward dates and events

- November 2024 – Update of CRIS to report financial and non-financial results for the 2023- 24 financial year.

9. CRIS approval and change register

Date of CRIS change	CRIS change	Approver	Basis of change
21 October 2016	Certification of the CRIS	Secretary Department of Health	New regulatory charging activity
02 November 2016	Agreement of the CRIS	Minister for Health	New regulatory charging activity
10 November 2016	Approval for the CRIS release	Finance Minister	High risk rating for the new regulatory charging activity
16 April 2019	Update of financial results and estimates.	Secretary Department of Health	2016-17 and 2017-18 financial results reported. 2018-19 and forward estimates updated.

Date of CRIS change	CRIS change	Approver	Basis of change
20 March 2020	Update of 2018/19 financial results	First Assistant Secretary – Regulatory Practice and Support Division	2018/19 financial results reported.
October 2020	Revision of fees and charges to reflect review of cost recovery arrangements and changes announced in 2020-21 Budget.	Minister for Health	Review of cost recovery cost recovery arrangements. Revised and new fees and charges.
July 2021	Annual update of CRIS and application of indexation to fees and charges for the 2021-22 financial year	Minister of Health and Aged Care	Annual update and review.
December 2021	Update of 2020-21 financial results	First Assistant Secretary – Regulatory Practice and Support Division	2020/21 financial results reported.
April 2023	Annual update of CRIS for the 2022-23 financial year, including actual financial results for the 2021-22 financial year	First Assistant Secretary – Regulatory Practice and Support Division	Annual update and review.
July 2023	Revision of fees and charges to reflect review of cost recovery arrangements and changes	Assistant Minister for Health and Aged Care	Review of the cost recovery arrangements approved in the 2023 Budget.
November 2023	Update of 2022-23 financial results	First Assistant Secretary – Regulatory Practice and Support Division	2022/23 financial results reported.
July 2024	Annual update of CRIS and application of indexation to fees and charges for the 2024-25 financial year	First Assistant Secretary – Regulatory Practice and Support Division	Annual update and review.